

**REMARKS**

This Amendment is in response to the Office Action dated April 6, 2004.

Applicants appreciate the careful consideration and favorable treatment of the claims in which claims 38-46 were allowed and claims 27-30 were indicated as containing allowable subject matter.

Claims 2-26 and 31-36 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite on the basis that the Examiner states that claim 2 fails to point out what the control unit controls responsive to the flow rates. Applicants have amended claim 2 to state that the control unit is configured to prevent flow of substitution fluid to the extracorporeal circuit by controlling flow of the diverted dialysate fluid within the second conduit when a certain event or condition occurs.

Claims 2, 4-5 and 18 stand rejected under 35 U.S.C. 102(b) as being anticipated by EP patent application No. 0526152. Applicants traverse this rejection based on the following comments and the foregoing amendments to the claims.

The cited EP application discloses an apparatus for hemodiafiltration treatment and includes a dialyzer (2); a differential flow meter (16) having two tubes transversed in countercurrent by the flow of liquid; and an electric unit (17) which generates a signal proportional to the mass flow rate difference between these flows. The conduit (8) branches from a duct that carries dialysate fluid to the dialyzer and infuses a quantity of liquid into the blood.

In contrast the present application discloses a diafiltration delivery module that is operatively attached to a dialysis machine and to the extracorporeal circuit. The diafiltration delivery module is in the form of a separate independent standalone module relative to the dialysis machine and the extracorporeal circuit. In other words, the claimed module is a separate unit that is





Claims 2-6 and 18 stand rejected under 35 U.S.C. 103(a) as being unpatentable over the '292 WO reference in view of Shaldon et al. Applicants respectfully submit that this rejection is now moot in view of the present amendment and should therefore be withdrawn. More specifically, neither of these cited references overcomes the deficiencies noted above, namely, that the claimed invention is a standalone module as opposed to an entire hemodiafiltration apparatus that has its own control unit that functions in the claimed manner of regulating flow of fluids within the module itself so as to influence the flow of substitution fluid.

In sum, these references do not overcome the deficiencies noted above and therefore, fail to disclose or suggest the claimed invention.

Claim 48 has been added and Applicants respectfully request consideration and allowance of claim 48. Claim 48 is similar to amended claim 2 and therefore should be allowed for the same reasons recited above as to why amended claim 2 should be allowed.

**Claims 38-46 stand allowed.**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

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Respectfully submitted,

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